

Message Text

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PAGE 01 STATE 306831
ORIGIN COME-00

INFO OCT-01 AF-08 ISO-00 EB-07 HEW-04 /020 R

DRAFTED BY COM/IEPR/OTP/GREDDING
APPROVED BY EB/OT/GCP:SAHMAD
COM/OTP/DND: LJMURPHY
FDA/BD/COMPLIANCE/RHAMILTON (PHONE)
FDA/BF/DRG/JSCHNABLY (DRAFT)
STATE/AF/W/RKOTT (IN SUB.)
COM/OIM/RBIDDLE (DRAFT)
STATE/AF/LWHITE (INFO.)
COM/OTP/TNAD/ARYDER

----- 055584 /12

R 180344Z DEC 76
FM SECSTATE WASHDC
TO AMEMBASSY LAGOS

LIMITED OFFICIAL USE STATE 306831

E.O. 11652: N/A

TAGS: ETRD, NI

SUBJECT: FREE SALE CERTIFICATES

REF: A. LAGOS 11985 B. STATE 229867 C. LAGOS 6295

1. REQUEST EMBASSY APPROACH FMG MINISTRY OF HEALTH WITH FOLLOWING REVISED PROPOSAL TO MEET REQUIREMENT FOR FREE SALE CERTIFICATES AS DESCRIBED IN FMG FOOD AND DRUG DECREE (NO. 35), 1974.

2. U.S. FOOD AND DRUG ADMINISTRATION (FDA) DOES NOT ISSUE QUOTE CERTIFICATE OF FREE SALE UNQUOTE FOR ARTICLES FOR EXPORT. HOWEVER, A FACTUAL STATEMENT OF STATUS OF A LIMITED OFFICIAL USE

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SPECIFIC ARTICLE SUBJECT TO FDA JURISDICTION MAY BE PROVIDED ON REQUEST. IN CASE OF ARTICLES REQUIRING PRE-MARKETING APPROVAL OR BATCH -CERTIFICATION (E.G., NEW DRUGS, NEW ANIMAL DRUGS, LICENSED BIOLOGICS, ANTIBIOTICS, INSULIN, AND COLORS), STATEMENT PROVIDES PRE-MARKET CLEARANCE STATUS OF ARTICLE. IN CASE OF ARTICLES

NOT SUBJECT TO PRE-MARKET CLEARANCE, SUCH AS FOODS, REQUESTOR (E.G., MANUFACTURER) MAY SUBMIT TO FDA COMPLETE INFORMATION ON COMPOSITION OF PRODUCT, METHOD OF PREPARATION, AND LABELING. IF PRODUCT COMPLIES WITH U.S. FOOD AND DRUG REGULATIONS, LETTER STATING THAT FDA HAS QUOTE NO

ADVERSE COMMENT UNQUOTE IS ISSUED TO MANUFACTURER. THIS EVALUATION DOES NOT REPEAT NOT GUARANTEE THE QUALITY OF ANY INDIVIDUAL BATCH OR SHIPMENT. INTERESTED THIRD PARTIES (E.G., SHIPPER OR IMPORTER) CAN REQUEST A QUOTE CERTIFIED COPY UNQUOTE OF THIS LETTER, BEARING OFFICIAL SEAL OF FDA. CERTIFIED COPY HAS GENERALLY BEEN ACCEPTED IN U.S. COURTS IN LIEU OF THE ACTUAL DOCUMENT. FOREIGN GOVERNMENTS HAVE ACCEPTED THIS CERTIFIED COPY AS EVIDENCE OF ACCEPTABILITY OF PRODUCT FOR FREE SALE IN U.S. FYI: SHOULD FMG ASK, FDA BUREAU OF DRUGS FILES INDICATE THAT BRAZIL AND LEBANON HAVE ACCEPTED THESE STATEMENTS. SINCE MOST LETTERS ARE ADDRESSED EITHER TO MANUFACTURER OR QUOTE TO WHOM IT MAY CONCERN UNQUOTE, MORE COMPLETE LIST UNAVAILABLE. END FYI.

3. THE USG AND FDA BEAR NO LEGAL RESPONSIBILITY FOR THE QUALITY AND/OR SAFETY OF ANY PRODUCT REVIEWED UNDER THIS PROCEDURE.

4. FDA CAN REVIEW ALL ARTICLES OF FOOD, DRUG, COSMETICS, OR DEVICE. IN OPINION OF USG THIS PROCEDURE COMPLIES FULLY WITH NIGERIAN REQUIREMENTS. REQUEST THAT FMG MINISTRY OF HEALTH ACKNOWLEDGE ACCEPTABILITY OF THESE PROCEDURES SO THAT FUTURE SUPPLY OF THESE PRODUCTS BY U.S. LIMITED OFFICIAL USE

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MANUFACTURERS WILL NOT BE DISRUPTED. UPON CONFIRMATION OF ACCEPTABILITY OF PROCEDURES, APPROPRIATE NOTIFICATION WILL BE GIVEN TO U.S. EXPORTERS AND MANUFACTURERS THROUGH REGULAR USDOC CHANNELS.

5. EXAMPLE OF FDA LETTER AND COPY OF FDA COMPLIANCE POLICY GUIDE NO. 7150.02 ENTITLED QUOTE REQUESTS FOR CERTIFICATE OF FREE SALE UNQUOTE BEING SENT BY AIRGRAM TO EMBASSY FOR USE IN PRESENTATION TO MINISTRY OF HEALTH.

KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOODS, CHEMICALS, EXPORT CONTROLS, COMMODITY AGREEMENTS
Control Number: n/a
Copy: SINGLE
Draft Date: 18 DEC 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: RELEASED
Disposition Approved on Date:
Disposition Authority: CunninFX
Disposition Case Number: n/a
Disposition Comment: 25 YEAR REVIEW
Disposition Date: 28 MAY 2004
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE306831
Document Source: CORE
Document Unique ID: 00
Drafter: IEPR/OTP/GREDDING
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760466-0109
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19761230/aaaaazfu.tel
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Locator: TEXT ON-LINE, ON MICROFILM
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Original Classification: LIMITED OFFICIAL USE
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: LIMITED OFFICIAL USE
Previous Handling Restrictions: n/a
Reference: 76 LAGOS 11985
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 27 JUL 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <27 JUL 2004 by BoyleJA>; APPROVED <18 OCT 2004 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FREE SALE CERTIFICATES
TAGS: ETRD, NI
To: LAGOS
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006